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REMARKS

As a preliminary matter, Applicants acknowledge and appreciate the allowability of Claims 5, 10 and 18.

Reconsideration of the above referenced application is respectfully requested. Upon entry of the foregoing amendment, Claims 1, 6-8, 10-11, 14-18, 20-23, 41, 47, 69, 95, 97 and 98-99 are currently pending. Claims 1-4, 9, 12-13, 19, 24-40, 42-46, 48-68, 70-94, 96 and 100-103 have been canceled without prejudice or disclaimer. Claims 6, 11, 14 and 69 have been amended. Basis for the amendments may be found throughout the specification and in the claims as originally filed. No new matter has been introduced and entry of the amendment is requested.

Rejections under 35 U.S.C. §112, second paragraph

Claims 1, 100, and 101 stand rejected under 35 U.S.C. §112, second paragraph as allegedly indefinite based on the statement on page 2 of the Office Action that claims 100 and 101 are outside of the scope of claim 1.

Applicants respectfully disagree, however, in the interest of expediting prosecution Claims 100 and 101 have been cancelled.

Claim 69 stands rejected under 35 U.S.C. §112, second paragraph as allegedly indefinite. Claim 69 has been amended to clarify that the claimed A549, W163, HeLa, Vero, 211, 211A and epithelial cell lines comprise SEQ ID NO: 32 or SEQ ID NO: 26.

Applicants respectfully submit that the grounds for the various rejections under 35 U.S.C. § 112, second paragraph have been obviated by the amendments described above. Withdrawal of the rejections is respectfully requested.

Rejections under 35 U.S.C. §112, first paragraph, written description.

Claims 1-4, 6-8 and 11 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons set forth on pages 4 - 6 of the Office Action.

Applicants respectfully disagree, however, in the interest of expediting prosecution Claims 1-4 have been canceled and Claims 6-8 and 11 are amended herein to depend from Claim 5. Claim 5 recites a specific TPL nucleotide set forth in SEQ ID NO:32.

Hence, one of ordinary skill in the art would be informed by the teachings of the subject specification, as to how to make an isolated nucleic acid molecule which contains the recited Ad TPL as set forth in Claims 6-8 and 11. In view of the above amendments and remarks, withdrawal of the rejection is respectfully requested.

Claims 14-17, 20-23 and 69 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking sufficient written description. The Office Action stats that the claims do not define what strains of adenoviruses and what structural proteins are within the scope of the claims. Claim 14 and claims dependent thereon have been amended herein to make reference to an adenovirus vector packaging cell line for packaging an adenovirus 5 vector, comprising a nucleic acid sequence that encodes an adenovirus structural protein selected from the group consisting of penton base, hexon, fiber, polypeptide IIIa, polypeptide V, polypeptide VI, polypeptide VII, polypeptide VIII, a chimeric protein and biologically active fragments thereof. Claims 15-17, 2-23 and 69 are all dependent upon Claim 14.

Accordingly, Applicants respectfully submit that the specification meets Applicants' written description burden under 35 U.S.C. 112, first paragraph, and the rejection should therefore be withdrawn.

Rejections under 35 U.S.C. §112, first paragraph, enablement.

Claims 1, 4, 6-8, 11, 14-17, 20-23, 41, 69, 95 and 97-101 stand rejected under U.S.C. §112, first paragraph as allegedly lacking enablement.

The first paragraph of 35 U.S.C. § 112 requires that the specification of a patent enable any person skilled in the art to which it pertains to make and use the claimed invention. Although the statute does not say so, enablement requires that the specification teach those in the art to make and use the invention without undue experimentation (e.g., *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir., 1991). An invention is enabled even though the disclosure

may require some routine experimentation to practice the invention. Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384, 231 U.S.P.Q. 81, 94 (Fed. Cir. 1986).

In accordance with the accepted standards of enablement set forth above, an invention is enabled if one skilled in the art could make and use the claimed invention without undue experimentation. Claims 1, 4, 100 and 101 have been canceled. Applicants submit that one of skill in the art could make and use the subject matter of Claims 6-8, 11, 14-18, 20-23, 41, 47, 69, 95, 97 and 98-99 without undue experimentation based on the information provided in the specification.

Claims 14-17, 20-23, 41, 69 and 95 stand rejected under U.S.C. §112, first paragraph as allegedly lacking enablement for the reason set forth on page 8 of the Office Action, where it is stated that the specification enables the 293, 211, 211A, but not the A549, W163 Hela, Vero and other uncharacterized cell lines.

It is Applicant's position that the specification teaches one of skill in the art how to make and use A549, W163 Hela, Vero and other uncharacterized cell lines, as set forth for example in paragraphs [0144] and [0294]. The Office Action states that this is not sufficient because the recited cell lines do not provide any Ad proteins that are required for packaging the vector. Current Claim 14 includes language to clarify that the recited cell lines serve to package an Ad 5 vector and that the packaging cell lines comprise a nucleic acid sequence that encodes an adenovirus structural protein selected from the group consisting of penton base, hexon, fiber, polypeptide IIIa, polypeptide V, polypeptide VI, polypeptide VII, polypeptide VIII, a chimeric protein which is operatively-linked to a promoter.

Compliance with the enablement requirement of Section 112, first paragraph, does not turn on whether an example is disclosed. (MPEP 2164.02). An applicant need not have actually reduced the invention to practice prior to filing. In *Gould v. Quigg*, 822 F.2d 1074, 1078, 3 USPQ 2d 1302, 1304 (Fed. Cir. 1987). The specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. In *re Borkowski*, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970).

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Applicants submit that one of skill in the art could make and use the subject matter of Claims 14-17, 20-23, 41, 69 and 95 without undue experimentation based on the specific information provided in the specification and claims. Therefore the rejection should be withdrawn.

Claims 1, 4, 6-8, 11, 100 and 101 stand rejected under U.S.C. §112, first paragraph as allegedly lacking enablement for the reason set forth on pages 9 and 10 of the Office Action, where it is stated that the specification, while being enabling for Ad5 TPL does not reasonably provide enablement for other TPL of different adenoviruses. Claims 1, 4, 100 and 101 have been canceled. Claims 6-8 and 11 depend from Claim 5 which recites a sequence of nucleotides encoding the adenovirus TPL nucleotide sequence set forth in SEQ ID NO: 32. Applicants submit that the specification teaches one of skill in the art how to make and use the current invention commensurate in scope with the current claims

In view of the above amendments and remarks, withdrawal of the enablement rejection under 35 U.S.C. § 112 is respectfully requested.

CONCLUSION

Applicants submit that the application is now in condition for examination on the merits. Early notification of such action is earnestly solicited. If any issues remain which the Examiner feels may be best resolved through a personal or telephonic interview, the Examiner is respectfully requested to contact Applicants counsel, Linda R. Judge at (415) 836-2586.

Respectfully submitted,



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